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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,405	12/06/2001	Yong-Ling Ruan	021565-110	5391
7590	06/30/2004		EXAMINER	
R. Danny Huntington, Esq. BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404			KALLIS, RUSSELL	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/003,405	RUAN ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 April 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 4-7 and 18-20 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3,8-17 and 21-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/21/4/12</u>	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-3, 8-17 and 21-30 in the reply filed on 4/26/2004 is acknowledged. The traversal is on the ground(s) that a complete search of both groups would necessarily overlap. This is not found persuasive because the two different methods have different method steps one requiring the expression of a DNA sequence that yields an RNA that is translated into protein and the other requiring the expression of a DNA sequence that yields an RNA that is capable of reducing expression of an endogenous sucrose synthase gene. The RNA expressed in either group is not required by the other group and thus a search of one method would not encompass a search of the other. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-30 are pending. Claims 1-3, 8-17 and 21-30 are examined.

Specification

The use of the trademark FIBERMAX has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. In the instant application Applicant's claim to priority as a CIP of a US provisional is incorrect. The first line of the specification should just claim priority to the provisional.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not identify the citizenship of each inventor, it does not claim priority to U.S. provisional 60/251,852 as indicated in the specification.

Claim Objections

Claims 1 and 15 are objected to because of the following informalities: The claims are drawn to non-elected subject matter, "said RNA being capable of reducing the expression of an endogenous sucrose synthase gene preferably an endogenous sucrose synthase gene expressed in fiber cells, preferably fiber initial cells; or". Applicant must amend claims to delete non-elected subject matter. Appropriate correction is required.

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Claims 8, 9 and 26 are objected to because of the following informalities: The claims are drawn to non-elected subject matter, in line 1 claims 4, 5, 6 and 7. Further, the claim should recite the claims in the alternative i.e. "any one of claims 1, 2 or 3".

Claims 21, 22 and 24 are objected to because of the following informalities: The claims are drawn to non-elected subject matter, in line 1 claims 18, 19 and 20. Further, the claim should recite the claims in the alternative i.e. "any one of claims 15, 16 or 17".

Claim 30 is objected to because of the following informalities: The claim should recite the claims in the alternative i.e. "any one of claims 11, 12, 13 or 14".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 8-17 and 21-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims a method for altering fiber development by providing cells of a plant with a chimeric gene comprising; either a coding region that yields an RNA capable of being translated into an active sucrose synthase protein; a nucleotide sequence of SEQ ID NO: 1; a nucleotide sequence encoding a polypeptide of SEQ ID NO: 2; a polynucleotide sequence having 70% sequence identity to a nucleotide sequence

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encoding SEQ ID NO: 2; a polynucleotide sequence having 70% sequence identity to SEQ ID NO: 1; a nucleotide sequence hybridizing under stringent conditions with a polynucleotide sequence encoding SEQ ID NO: 2; a nucleotide sequence hybridizing under stringent conditions with a polynucleotide sequence comprising SEQ ID NO: 1; or a part of an RNA capable of being translated into an active sucrose synthase protein that encodes an active sucrose synthase protein.

Applicant describes a nucleic acid sequence of SEQ ID NO: 1 and an amino acid sequence of SEQ ID NO: 2; and lists the GenBank Accession numbers or several sucrose synthase sequences known in the art on pages 14-18 of the specification.

Applicant does not describe a polynucleotide sequence having 70% sequence identity to SEQ ID NO: 1; a nucleotide sequence hybridizing under stringent conditions with a polynucleotide sequence encoding SEQ ID NO: 2; a nucleotide sequence hybridizing under stringent conditions with a polynucleotide sequence comprising SEQ ID NO: 1; or a part of an RNA capable of being translated into an active sucrose synthase protein that encodes an active sucrose synthase protein.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding an active sucrose synthase protein falling within the scope of the claimed genus of a polynucleotide sequence having 70% sequence identity to SEQ ID NO: 1; a nucleotide sequence hybridizing under stringent conditions with a polynucleotide sequence encoding SEQ ID NO: 2; a nucleotide sequence hybridizing under stringent conditions with a polynucleotide sequence comprising SEQ ID NO: 1; or a part of an RNA or polynucleotide capable of being translated into an active sucrose synthase protein that retains sucrose synthase activity.

Applicants only describe a single cDNA from cotton of SEQ ID NO: 1 encoding SEQ ID NO: 2 and lists GenBank Accession numbers of sucrose synthases known in the art. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*.

Furthermore, given the lack of description of the necessary elements essential for sucrose synthase protein activity, it remains unclear what features identify a sucrose encoding polynucleotide or which part of an RNA or polynucleotide encoding a sucrose synthase would retain sucrose synthase activity. Since the genus of sucrose synthase encoding polynucleotides as claimed has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

A nucleotide sequence hybridizing under stringent conditions with a polynucleotide sequence encoding SEQ ID NO: 2; a nucleotide sequence hybridizing under stringent conditions with a polynucleotide sequence comprising SEQ ID NO: 1; a

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polynucleotide sequence having 70% sequence identity to a nucleotide sequence encoding SEQ ID NO: 2; or a polynucleotide sequence having 70% sequence identity to SEQ ID NO: 1 encompass naturally occurring allelic variants, polynucleotides encoding mutants of sucrose synthase proteins, as well as sequences encoding proteins having no known sucrose synthase activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of polynucleotides encompassed by the hybridization language or percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Claims 1-3, 8-17 and 21-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to a method for altering fiber development or properties, a method of improving fiber yield, a method of improving fiber quality, and a method of increasing seed size by providing cells of plants with a polynucleotide capable of being translated into an active sucrose synthase, and plants and seeds provided therewith.

Applicants provide guidance for reducing fiber and seed development in cotton transformed with antisense and co-suppression constructs comprising an undefined polynucleotide encoding an unspecified sucrose synthase (Example 1 page 25).

The specification fails to provide guidance for using the other polynucleotides encompassed by the claims that encode an active sucrose synthase that would alter fiber development, improve fiber yield, improve fiber quality, or increase seed size by providing cells of plants with a polynucleotide capable of being translated into an active sucrose synthase. Applicants fail to teach which sucrose synthase encoding polynucleotides would alter fiber development other than SEQ ID NO: 1. Further, Applicant does not teach any increases or improvements in fiber quality, or size; or any increases in seed size using any of the sucrose synthases taught in the specification.

The state of the art for transformation of a plant with a sucrose synthase encoding polynucleotide in order to increase or alter fiber development is unpredictable because there are multiple isoforms of sucrose synthase that are drawn to somewhat different enzymatic activities producing different products in different plant cells in different plant organs. Three isoforms of pea sucrose synthase were cloned and characterized. It was observed in mutants of the pea sucrose synthase that some isoforms were active in the production of starch and others were active in the production of cellulose and that the

sequence identity among the clones covers a narrow range from 68 to 87 percent identity (Barratt D. et al. Plant Physiology, October 2001 Vol. 127; pp. 655-664; see abstract and page 656, column 1, 1st paragraph of the Results section). Different isoforms of sucrose synthase serving separate physiological roles is also seen in other plant species. For example, the corn SS1 isoform of sucrose synthase plays the dominant role in providing carbon for cellulose biosynthesis while SS2 serves to provide carbon precursors for starch biosynthesis (Chourey P. et al. Mol. Gen. Genet. 1998, Vol. 259, pp. 88-96; see abstract and page 89 column 1, last paragraph of the introduction).

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by *in vitro* testing for cellulose synthesizing activity or by *in vivo* transformation and analysis of fiber properties or development, in order to identify those sucrose synthase isoforms that when expressed in a plant would produce plants with an altered fiber development or properties, or improve fiber yield, improve fiber quality, or increase seed size by providing cells of plants as broadly claimed.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 contains the trademark/trade name FIBERMAX. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a cotton plant and, accordingly, the identification/description is indefinite.

Claims 1-3, 8-17 and 21-30 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a method for altering fiber development or properties, a method of improving fiber yield, a method of improving fiber quality, and a method of increasing seed size by providing cells of plants with a polynucleotide capable of being translated into an active sucrose synthase, and plants and seeds provided therewith.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
June 6, 2004

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